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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,359

07/15/2004

Domenico Fanara

2004_1045A

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12/11/2008

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WASHINGTON, DC 20006-1021

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,359	Applicant(s) FANARA ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed August 28, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Applicant's Arguments

The arguments are now moot due to the withdrawal of the previous rejections. Although Applicant has narrowed the scope of the claim to encompass specific ingredients in specific amounts, these ingredients are known in the art as being components used in chewing gum compositions comprising pharmaceutical agents. It was previously asserted by Applicant that there were unexpected results due to the separation of sweeteners such as mannitol from the active cetirizine. The alleged unexpected results have not been factually demonstrated.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen (US 2004/0028772) in view of Cherukuri et al. (US 4,238,510) and Reiner et al. (US 5,711,961).

Andersen discloses a chewing gum composition comprising an active ingredient. The gum base comprises 15-99%, the active agent comprises 0.001-75%, optionally

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flavor up to 5%, optionally one or more high potent sweeteners 0.01-5%, optionally one or more solubilizers and bulk sweetener q.s. ad 100%, all w/w (paragraphs 0068-0074). Active agents include cetirizine (paragraphs 0110 and 0192). Bulk sweeteners include maltose, dextrin, hydrogenate starch hydrolysates and isomalt. High potent sweeteners include aspartame and acesulfame (paragraph 0138). The sweeteners may be used in combination. The chewing gums may also comprise solubilizers such as cyclodextrins that affect the release of medicinal substances. Fillers included in the gums include talc and silicium oxide, e.g. colloidal silica¹ (paragraph 0128). Softeners include magnesium stearate (paragraph 0142). The chewing gums include a coating, which may include wax, a film coating or a conventional so-called candy coat based on sugar-containing or sugar free substances. Waxes include carnauba wax (paragraph 0132). Sugar sweeteners, which are considered sugarless, include mannitol and starch hydrolysates (paragraph 0137). The coating may or may not comprise the active agent. The reference differs from the instant claim insofar as it does not disclose the specific components that make up the coating or the amounts.

Cherukui et al. disclose coatings for chewing gum compositions. The coatings comprise sweeteners such as xylitol and mannitol with a concentration ranging from 0.05 to about 90% (col. 5, lines 13-21), dispersing compounds such as titanium dioxide, an adhesive component such as gum arabic (col. 2, lines 65-68), and flavoring (col. 4, lines 39-42). The reference differs from the instant claims insofar as it does not disclose

¹ Butlers et al. EP 1 930 381, page 3, line 56.

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the gum center comprise cetirizine, polyethylene glycol 6000, carnauba wax and all of the recited components in the core.

Reiner et al. is used as a general teaching to disclose components used in lacquer coatings for chewing gums. These include waxes and polyethylene glycol. The film coatings may comprise polyethylene glycol 6000 (col. 2, lines 45-48). The gums are also sprayed with a wax such as carnauba wax (col. 2, lines 62 and 63). The reference differs from the instant claims insofar as it does not disclose all of the other recited components of the core and coating such as cetirizine, cyclodextrin, colloidal silica, talc, mannitol, arabic gum and xylitol.

It would have been obvious to one of ordinary skill in the art to have used the sugarless coating formulations as the coatings for chewing gums of the Andersen motivated by the desire to use a coating disclosed in the art as useful for chewing gums, candies and medicinal compositions, as disclosed by Cherukuri et al..

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to have used polyethylene glycol 6000 in the combined chewing gums of the Andersen and Cherukui et al. motivated by the desire to produce a coating having certain characteristic such as a lacquer.

In regards to the cyclodextrin being beta cyclodextrin, it would have been obvious to use a cyclodextrin in the compositions of the primary reference motivated by the

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desire to use a cyclodextrin that is disclosed in the art as commercially available with a high purity and able to reduce degradation of pharmaceutical agents².

In regards to the recited amounts of the instant claims, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05 II. It is in the relative skill of one of ordinary skill in the art to adjust each component to obtain a chewing gum composition with the desired properties based on concentration ranges disclosed by the prior art for each of the components. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the amount of each component based on the amounts used in the prior art and to obtain the desired characteristics.

Claim 39 is rejected.

No claim allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

² Testa (US 5,866,179), col. 2, lines 12-63.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612